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| The PBAC agenda primarily consists of applications relating to the new listing of a drug or vaccine on the PBS or the National Immunisation Program.The PBAC agenda consists of the following:**1 Minutes of Previous Meeting****2 Chairman’s report (verbal)****3 Matters arising from the minutes****4 Matters arising/outstanding****5 New drug applications****6 Requests for changes to listings****7 Resubmissions****8 Pricing Matters****9 Matters relating to PBS review****10 Subcommittee and Working Party reports****11 Other business****12 Correspondence****13 Further information****14 Late papers****15 Tabled papers**Consumers will have the opportunity to provide comments on new drug submissions (item 5), changes to listings (item 6) and resubmissions (item 7). In many circumstances, consumers will be able to comment on items in other sections of the agenda. The submissions for which input is sought will be listed in alphabetical order by drug name. There is no provision for consumer comments to the PBAC on agenda item 8 which relates to pricing matters. Pharmaceutical benefits listed in the Schedule fall into three broad categories:*Unrestricted benefits* – have no restrictions on their therapeutic uses; *Restricted benefits* – can only be prescribed for specific therapeutic uses (noted as Restricted benefit); and *Authority required benefits* – Authority required benefits fall into two categories: * *Authority required benefits* require prior approval from Medicare Australia or the DVA (noted as Authority required)
* *Authority required (STREAMLINED) benefits* do not require prior approval from Medicare Australia or the DVA but require the recording of a streamlined authority code (noted as Authority required (STREAMLINED)).

Submissions are categorised broadly as major or minor:* *Major:* Submissions to list new medicines on the Schedule of Pharmaceutical Benefits or to make substantial changes to current listings are generally classified as major submissions. Major submissions require presentation of an economic evaluation.
* *Minor:* Submissions that relate to new forms of previously listed products and changes to the conditions of use e.g. change in maximum quantity/repeats or clarifying the wording of a restriction (while not altering the intended use) are considered to be minor submissions. Minor submissions do not usually require the presentation of an economic evaluation.
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| **Submission type**(new listing, change to listing) | **Drug Name, form(s), strength(s) and Sponsor**(Drug name, form, strength, Trade name®, Sponsor) | **Drug Type and Use**(What is the drug used to treat?) | **Listing requested by Sponsor / Purpose of Submission**(Includes type of listing requested (unrestricted, restricted benefit, authority required) and restriction wording. If restriction is lengthy it may be paraphrased.) |
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| Change to listing(Major Submission) | ALEMTUZUMABSolution concentrate for I.V. infusion 12 mg in 1.2 mLLemtrada®Sanofi-Aventis Australia Pty Ltd | Relapsing remitting multiple sclerosis(RRMS) | To request a change to the existing listing to allow for retreatment of RRMS with two additional courses of treatment in patients who have had an initial two courses of treatment. |
| Change to listing(Minor Submission) | AMINO ACIDS-SYNTHETIC, FORMULAOral powder 400 g (Neocate Junior Vanilla)Neocate Junior® VanillaNutricia Australia Pty Limited | Cow’s milk allergy, multiple protein food intolerance and other medical conditions where an elemental diet is required | To request a formulation change to the existing Authority Required listing of Neocate Junior Vanilla.  |
| New listing(Major Submission) | APALUTAMIDETablet 60 mg Erlyand®Janssen-Cilag Pty Ltd  | Castration resistant prostate cancer | To request an Authority Required listing for the treatment of non-metastatic castration resistant prostate cancer in combination with androgen deprivation therapy.  |
| Change to listing(Major Submission) | BOTULINUM TOXIN TYPE ALyophilised powder for injection 100 unitsBotox®Allergan Australia Pty Ltd | Focal spasticity of the lower limb | Resubmission to request an extension to the current Section 100 (Botulinum Toxin Program) listing to include the treatment of lower limb focal spasticity in adults following stroke, who meet certain conditions. |
| Change to listing(Minor Submission) | BRENTUXIMAB VEDOTINPowder for I.V. infusion 50 mgAdcetris®Takeda Pharmaceuticals Australia Pty Ltd | Cutaneous T-cell lymphomas (CTCL) | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of refractory or relapsed CD30 positive cutaneous T-cell lymphomas (CTCL). |
| New listing(Major Submission) | BUPRENORPHINEInjection 8 mg in 0.16 mL pre-filled syringe Injection 16 mg in 0.32 mL pre-filled syringeInjection 24 mg in 0.48 mL pre-filled syringeInjection 32 mg in 0.64 mL pre-filled syringeInjection 64 mg in 0.18 mL pre-filled syringeInjection 96 mg in 0.27 mL pre-filled syringeInjection 128 mg in 0.36 mL pre-filled syringeBuvidal®Camarus AB | Opiate dependence | To request a Section 100 (Opiate Dependence Treatment Program) listing for the treatment of patients with opiate dependence.  |
| Change to listing(Minor Submission) WITHDRAWN | CABOZANTINIB Tablet 20 mg Tablet 40 mgTablet 60 mgCabometyx® Ipsen Pty Ltd | Clear cell variant renal cell carcinoma (RCC) | To request an amendment to the current restriction to allow use of cabozantinib in patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal.  |
| Change to listing(Minor Submission) | CARFILZOMIBPowder for injection 30 mgPowder for injection 60 mgKyprolis®Amgen Australia Pty Ltd | Multiple myeloma | To request an amendment to the restriction for pomalidomide (sponsored by Celgene Pty Limited) to allow the use of any proteasome inhibitor (bortezomib or carfilzomib) prior to treatment with pomalidomide.  |
| Change to listing(Major Submission) | CLOSTRIDIUM BOTULINUM TYPE A TOXIN – HAEMAGGLUTININ C COMPLEX Lyophilised powder for I.M. injection 300 unitsLyophilised powder for I.M. injection 500 unitsDysport®Ipsen Pty Ltd | Spasticity of the lower limb  | To extend the current Section 100 (Botulinum Toxin Program) listing to include the treatment of patients with moderate to severe spasticity of the lower limb following an acute event. |
| Change to listing(Major Submission) | CLOSTRIDIUM BOTULINUM TYPE A TOXIN – HAEMAGGLUTININ C COMPLEX Lyophilised powder for I.M. injection 300 unitsLyophilised powder for I.M. injection 500 unitsDysport®Ipsen Pty Ltd | Spasticity of the upper limb  | To extend the current Section 100 (Botulinum Toxin Program) listing to include treatment of patients with moderate to severe spasticity of the upper limb following an acute event, and to remove the current restriction on the number of treatment periods in a lifetime |
| New listing(Major Submission) | CRISABOROLEOintment containing crisaborole 20 mg per g, 60 gStaquis®Pfizer Australia Pty Ltd | Atopic dermatitis | To request an Authority Required (STREAMLINED) listing for the treatment of mild to moderate atopic dermatitis in patients who have failed to achieve satisfactory disease control with, or are contraindicated to, topical corticosteroids.  |
| New listing(Minor Submission) | DENOSUMABInjection 120 mg in 1.7 mLXgeva®Amgen Australia Pty Limited | Multiple myeloma | Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of multiple myeloma.  |
| New listing(Major Submission) | DURVALUMABSolution for I.V. infusion 120 mg in 2.4 mLSolution for I.V. infusion 500 mg in 10 mLImfinzi®AstraZeneca Pty Ltd | Non-small cell lung cancer  | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of patients with unresectable Stage III non-small cell lung cancer.  |
| New listing(Major Submission) | ENCORAFENIB and BINIMETINIBEncorafenib:capsule 50 mgcapsule 75 mg Binimetinib:tablet 15 mgBRAFTOVI® and MEKTOVI®Pierre Fabre Australia Pty Ltd | Melanoma | To request an Authority Required (STREAMLINED) listing for the concurrent use of encorafenib and binimetinib for the treatment of BRAFV600 mutation positive unresectable Stage III or metastatic (Stage IV) melanoma. |
| New listing(Major Submission)WITHDRAWN | ERENUMABInjection 70 mg in 1 mL single dose pre-filled penAimovig®Novartis Pharmaceuticals Australia Pty Ltd  | Episodic migraine | To request an Authority Required (STREAMLINED) listing for prophylaxis in patients with episodic migraine. |
| Change to recommended listing(Minor Submission) | ETANERCEPTInjection 50 mg in 1 mL single use auto-injector, 4;Injections 50 mg in 1 mL single use pre-filled syringes, 4Brenzys®Merck Sharp & Dohme (Australia) Pty Limited | Severe active rheumatoid arthritisAnkylosing spondylitisSevere psoriatic arthritisSevere chronic plaque psoriasis | To request changes to the current Initial 1, Initial 2 and First Continuing restrictions for Brenzys®, including changing the restriction level to allow telephone authority. |
| New listing(Minor Submission) | FERRIC CARBOXYMALTOSEInjection 1 g (iron) in 20 mLFerinject®Vifor Pharma Pty Limited | Iron deficiency anaemia | To request an unrestricted benefit listing for a new strength of iron injection. |
| Change to listing(Minor Submission) | FLUTICASONE PROPIONATE with EFORMOTEROLPressurised inhalation containing fluticasone propionate 50 micrograms with formoterol fumarate dihydrate 5 micrograms per dose, 120 doses;Pressurised inhalation containing fluticasone propionate 125 micrograms with formoterol fumarate dihydrate 5 micrograms per dose, 120 doses;Pressurised inhalation containing fluticasone propionate 250 micrograms with formoterol fumarate dihydrate 10 micrograms per dose, 120 dosesFlutiform® 50/5, 125/5, 250/10Mundipharma Pty Ltd | Asthma | To request the current Authority Required (STREAMLINED) listing be amended to a Restricted Benefit. |
| New listing(Minor Submission) | FOLLITROPIN ALFA with LUTROPIN ALFAInjection 900 I.U. - 450 I.U. in 1.44 mL multi-dose cartridgePergoveris®Merck Serono Australia Pty Ltd | Stimulation of follicular development | To request a Section 100 (IVF program) listing of a new form of follitropin alfa with lutropin alfa. |
| New listing(Minor Submission) | GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALSOral liquid 250 mL, 30 (PKU Glytactin RTD 15 Lite)PKU Glytactin RTD 15 LITECortex Health Pty Ltd | Phenylketonuria (PKU) | To request a Restrict Benefit listing for the treatment of PKU. |
| New listing(Minor Submission) | GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID WITH LOW PHENYLALANINESachets containing oral powder 33.3 g, 16 (PKU GMPro)PKU GMProNutricia Australia Pty Limited | Phenylketonuria (PKU) | To request a Restricted Benefit listing for the treatment of PKU. |
| Change to listing(Minor Submission) | HYPROMELLOSEEye drops 3 mg per mL, 10 mLIn a Wink Moisturising®, Genteal®Alcon Laboratories (Australia) Pty Ltd | Severe dry eye syndrome, including Sjogren's syndrome | To request a change in pack size for the In a Wink Moisturising® and Genteal® brands of hypromellose. |
| Change to listing(Major Submission) | INACTIVATED QUADRIVALENT INFLUENZA VACCINE (SPLIT VIRION)Injection 0.5mL in pre-filled syringeAfluria® QuadSeqirus Australia Pty Ltd | Prevention of seasonal influenza | To extend the current National Immunisation Program (NIP) listing to include persons aged 5-17 years who are currently eligible for vaccination through the NIP with other brands of influenza vaccine. |
| New listing(Major Submission) | INOTUZUMAB OZOGAMICINPowder for I.V. infusion 1 mg Besponsa®Pfizer Australia Pty Ltd | Acute lymphoblastic leukaemia (ALL) | To request a Section 100 (Efficient Funding of Chemotherapy) listing for the treatment of relapsed or refractory CD22 positive B-cell precursor acute lymphoblastic leukaemia (ALL).  |
| New listing(Major Submission) | INSULIN ASPARTInjections (human analogue), pre filled pen, 100 units per mL, 3mLInjections (human analogue), vial, 100 units per mL, 10 mLInjections (human analogue), cartridges, 100 units per mL, 3 mLFiasp®Novo Nordisk Pharmaceuticals Pty Ltd | Diabetes Mellitus | To request an unrestricted benefit listing for diabetes mellitus.  |
| New listing(Minor Submission) | ISOTRETINOINCapsule 5 mgOratane®Oraderm Pharmaceuticals Pty Ltd | Severe cystic acne | To request an Authority Required (STREAMLINED) listing of a new strength of isotretinoin for the treatment of severe cystic acne.  |
| Change to listing(Major Submission) | LACOSAMIDETablet 50 mgTablet 100 mgTablet 150 mgTablet 200 mgOral liquid 10 mg per mL, 200 mL Vimpat®UCB Pharmaceuticals Pty Ltd | Partial epileptic seizures | To request an Authority Required (STREAMLINED) listing for the treatment of intractable partial epileptic seizures for patients aged 4 to 15 years.  |
| New listing(Minor Submission) | LENVATINIBCapsule 4 mg (as mesilate)Lenvima®Eisai Australia Pty Ltd | Hepatocellular carcinoma | Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of patients with unresectable hepatocellular carcinoma. |
| New listing(Minor Submission) | NIVOLUMAB and IPILIMUMABnivolumab: Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mLipilimumab: Injection concentrate for I.V. infusion 50 mg in 10 mL Injection concentrate for I.V. infusion 200 mg in 40 mL Opdivo® and Yervoy®Bristol-Myers Squibb Australia Pty Ltd |  Renal cell carcinoma (RCC) | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STEAMLINED) listing for the concurrent use of nivolumab and ipilimumab for the treatment of Stage IV clear cell variant renal cell carcinoma (RCC).  |
| New listing(Major Submission) | OBETICHOLIC ACIDTablet 5 mgTablet 10 mgOcaliva®Emerge Health Pty Ltd | Primary biliary cholangitis | To request an Authority Required (STREAMLINED) listing for the treatment of patients with primary biliary cholangitis. |
| New listing(Minor Submission) | OSIMERTINIBTablet 40 mg Tablet 80 mgTagrisso®Astra Zeneca Pty Ltd | Non-small cell lung cancer (NSCLC) | Resubmission to request an Authority Required listing for the treatment of patients with locally advanced or metastatic epidermal growth factor (EGFR) T790M mutation positive non-small cell lung cancer (NSCLC) who have progressed on or after prior treatment with an EGFR tyrosine kinase inhibitor (TKI). |
| New listing(Minor Submission) | PEGFILGRASTIMInjection 6 mg in 0.6 mL single use pre-filled syringeFulphila®Alphapharm Pty Ltd  | Chemotherapy-induced neutropenia | Resubmission to request a Section 100 (Highly Specialised Drug) Authority Required (STREAMLINED) listing of this biosimilar brand for all indications for which the reference biologic is currently PBS listed. |
| Change to listing(Minor Submission) | PEMBROLIZUMABSolution concentrate for I.V. infusion 100 mg in 4 mLKeytruda®Merck Sharp & Dohme (Australia) Pty Ltd | Melanoma | To request removal of the weight-based dosing option for pembrolizumab in unresectable stage III or Stage IV malignant melanoma. |
| Change to listing(Major Submission) | PEMBROLIZUMABSolution concentrate for I.V. infusion 100 mg in 4 mLKeytruda®Merck Sharp & Dohme (Australia) Pty Ltd | Melanoma | To request Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing as an adjuvant to complete surgical resection for Stage III or Stage IV malignant melanoma.  |
| Change to listing(Major Submission) | PEMBROLIZUMABSolution concentrate for I.V. infusion 100 mg in 4 mLKeytruda®Merck Sharp & Dohme (Australia) Pty Ltd | Non-small cell lung cancer (NSCLC) | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing, in combination with platinum chemotherapy and pemetrexed, for the treatment of EGFR wildtype ALK translocation negative non-squamous NSCLC. |
| Change to listing(Major Submission) | PEMBROLIZUMABSolution concentrate for I.V. infusion 100 mg in 4 mLKeytruda®Merck Sharp & Dohme (Australia) Pty Ltd | Primary mediastinal B-cell lymphoma (PMBCL) | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of patients with relapsed or refractory PMBCL who meet certain conditions.  |
| Change to listing(Major Submission) | PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE, 13-VALENT ADSORBEDInjection 0.5 mL in pre-filled syringePrevenar-13®Pfizer Australia Pty Ltd | Prevention of pneumococcal disease | To expand the current National Immunisation Program (NIP) listing to include:- children aged 5 to 14 years;- adults aged 15 to 64 years with increased risk of pneumococcal disease; and - Aboriginal and Torres Strait Islander adults aged 25 years and older. |
| Change to listing(Minor Submission) | PONATINIBTablet 15 mg (as hydrochloride)Tablet 45 mg (as hydrochloride)Iclusig®Specialised Therapeutics Australia Pty Ltd | Chronic myeloid leukaemia (CML) | To request amendments to the circumstances under which ponatinib is subsidised for the treatment of CML. |
| New listing(Major Submission) | REGORAFENIBTablet 40 mg (as monohydrate)Stivarga®Bayer Australia Ltd | Hepatocellular carcinoma (HCC) | Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of patients with unresectable HCC who have progressed on sorafenib treatment. |
| New listing(Minor Submission) | RILUZOLEOral liquid 50 mg per 10 mL, 300 mLTeglutik®Seqirus (Australia) Pty Ltd | Amyotrophic lateral sclerosis (ALS) | To request an Authority Required listing of an oral liquid form of riluzole for the treatment of ALS. |
| Change to listing(Major Submission) | RIVAROXABANTablet 10 mgXarelto®Bayer Australia Ltd | Venous thromboembolism | To request an Authority Required (STREAMLINED) listing for the prevention of recurrent venous thromboembolism. |
| New listing(Major Submission) | ROMOSOZUMABInjection 105 mg in 1.17 mL pre-filled penInjection 105 mg in 1.17 mL pre-filled syringeEvenity®Amgen Australia Pty Ltd | Osteoporosis | To request an Authority Required listing for the treatment of patients with severe osteoporosis. |
| New listing(Major Submission) | SAFINAMIDETablet 50 mg Tablet 100 mg Xadago®Seqirus Australia Pty Ltd | Parkinson disease | To request a restricted benefit listing for the treatment of patients with Parkinson disease, as add-on therapy to a regimen that includes levodopa, in patients experiencing motor fluctuations. |
| Change to listing(Minor Submission) | SAPROPTERINTablet (soluble) containing sapropterin dihydrochloride 100 mgKuvan®BioMarin Pharmaceutical Australia Pty Ltd | Hyperphenylalaninemia (HPA) | Resubmission to request an Authority Required listing for the treatment of HPA in patients with phenylketonuria. |
| New listing(Major Submission) | SARILUMABInjection 200 mg in 1.14 mL pre-filled syringeInjection 150 mg in 1.14 mL pre-filled syringeKevzara®Sanofi-Aventis Australia Pty Ltd | Rheumatoid arthritis  | To request an Authority Required listing for the treatment of patients with severe active rheumatoid arthritis. |
| Change to listing(Minor Submission) | SEASONAL INFLUENZA VACCINESInjection 0.5 mL in pre-filled syringeAfluria® QuadFluQuadri®Fluarix Tetra®Seqirus (Australia) Pty LtdSanofi-Aventis Australia Pty LtdGlaxoSmithKline Australia Pty Ltd | Prevention of seasonal influenza | To request listing of seasonal influenza vaccines on the National Immunisation Program (NIP) for Aboriginal and Torres Strait Islander children and adolescents aged 5 - 14 years. |
| New listing(Major Submission) | TESTOSTERONETransdermal gel (pump pack) 23 mg per 1.15 g dose, 56 dosesTestavan®Ferring Pharmaceuticals Pty Ltd | Androgen deficiency;Micropenis;Pubertal induction;Constitutional delay of growth or puberty | To request an Authority Required listing for the treatment of male hypogonadism. |
| Change to listing(Major Submission) | TIOTROPIUMSolution for oral inhalation 2.5 micrograms (as bromide monohydrate) per actuation (60 actuations)Spiriva® Respimat®Boehringer Ingelheim Pty Ltd | Asthma | Resubmission to extend the current Authority Required (STREAMLINED) listing to include treatment of severe asthma for children and adolescents aged 6 to 17 years. |
| Change to listing(Major Submission) | TOCILIZUMABInjection 162 mg in 0.9 mL pre-filled penInjection 162 mg in 0.9 mL pre-filled syringeActemra®Roche Products Pty Ltd | Giant Cell Arteritis | To request an Authority Required listing for the treatment of giant cell arteritis. |
| Change to listing(Major Submission) | TOFACITINIBTablet 5 mgXeljanz®Pfizer Australia Pty Ltd | Psoriatic arthritis | To request an Authority Required listing for the treatment of patients with severe active psoriatic arthritis who have had an inadequate response to methotrexate and disease modifying anti-rheumatic drugs. |
| New listing(Major Submission) | VARICELLA ZOSTER RECOMBINANT VACCINEInjection [1 vial] (&) adjuvant substance diluent [0.5 mL vial], 1 packShingrix®GlaxoSmithKline Australia Pty Ltd | Prevention of herpes zoster | To request National Immunisation Program (NIP) listing for the prevention of herpes zoster in adults aged 60 years with a 5 year catch-up program for persons aged over 60 years.  |
| New listing(Major Submission) | VENETOCLAXTablet 10 mgTablet 50 mgTablet 100 mgVenclexta®AbbVie Pty Ltd | Relapsed or refractory chronic lymphocytic leukaemia | To request an Authority Required listing, in combination with rituximab, for the treatment of patients with relapsed or refractory CLL who are unsuitable for treatment with a purine analogue. |
| Subcommittee report(DUSC Analysis Submission) | BEVACIZUMABAvastin®Roche Products Pty Ltd | Advanced Stage IIIB, IIIC or Stage IV epithelial ovarian, fallopian tube or primary peritoneal cancer | To compare the predicted and actual use of bevacizumab for Advanced International Federation of Gynecology and Obstetrics (FIGO) Stage IIIB, IIIC or Stage IV epithelial ovarian, fallopian tube or primary peritoneal cancer since PBS listing for these indications. |
| Subcommittee report(DUSC Analysis Submission) | Daclatasvir Grazoprevir with elbasvir Ledipasvir with sofosbuvir Paritaprevir with ritonavir with ombitasvir and dasabuvir and ribavirin RibavirinSofosbuvir Sofosbuvir with velpatasvir Peginterferon alfa-2aDaklinza®Zepatier®Harvoni®Viekira Pak-RBV®Sovaldi®Epclusa®Pegasys®AbbVie Pty LtdBristol-Myers Squibb Australia Pty LtdClinect Pty LtdGilead Sciences Pty LimitedMerck Sharp & Dohme (Australia) Pty LtdRoche Products Pty Ltd | Chronic hepatitis C infection  | To review the use of direct acting antiviral medicines listed on the PBS for the treatment of chronic hepatitis C infection. |
| Subcommittee report(DUSC Analysis Submission) | FEBUXOSTATAdenuric®A. Menarini Australia Pty Limited | Chronic gout | To compare the predicted and actual use of febuxostat for the treatment of chronic gout since PBS listing. |
| Subcommittee report(DUSC Analysis Submission) | RUXOLITINIBJakavi®Novartis Pharmaceuticals Australia Pty Limited | Myelofibrosis | To compare the predicted and actual use of ruxolitinib for intermediate-1, intermediate-2 and high risk myelofibrosis since PBS listing. |
| PBS review(Other Submission) | Post-market Review of Pulmonary Arterial Hypertension (PAH) MedicinesBosentanAmbrisentanMacitentanEpoprostanolIloprostSildenafilTadalafilRiociguat(all listed brands) | Pulmonary Arterial Hypertension | To consider the findings of the Post-Market Review of PBS medicines for Pulmonary Arterial Hypertension (PAH). |